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10/507,359	09/10/2004	Johan Bernard Ubbink	115808-504	5698
29157 7590 01/24/2008 BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER BADR, HAMID R	
			ART UNIT 4174	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

DETAILED ACTION

Response to Amendment

The amendment filed on 11/21/2007 is acknowledged.

Claims 1-14 are being considered on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 3-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okonogi et al. (US 4888171) in view of Klapwijk et al. (EP 0 298 605) and Van Lengerich (WO 99/48372).

3. Okonogi et al. disclose a granular product containing dried viable microorganism cells, which has been protected against permeation of environmental moisture and atmospheric oxygen (Col. 2, lines 36-39). They also teach of the materials used in the formation of the core of their product (Col. 3, lines 9-23). The coating of their product is explained in terms of the composition and function. They teach of the use of the binding materials for coating the product in order to protect it against permeation of the environmental moisture and atmospheric oxygen. They further explain the use of shellac or zein for enteric coating (Col. 5, lines 17-34; Col. 8, lines 33-46). They specify

their granular product to have a mean diameter of 1.5 mm (Col. 9, lines 1-2). Assuming a spherical shape, the mean granule volume is calculated to be 0.99 mm^3 .

4. Okonogi et al. give details of making a granular product containing dried viable bacterial cells, the product being substantially free of water (Claims 1 and 4). They also mention that the water content of the core material is preferably as low as possible, less than 5% (w/w) (Col. 3, lines 22-23).

5. Okonogi et al. disclose the viable count of lactic acid bacteria in their product to be 14×10^8 cells/g. The survival rate has been calculated to be 98% (Col. 9, lines 6-13). It is claimed that the cell survival rate in their product exceeds that of the conventional product during prolonged storage periods (Abstract, Table 1, Table 2, Table 3).

6. Okonogi et al. teach of the materials to be used for composing the core of their product. They clearly teach of materials such as sugar or sugar/starch composition (fillers) which can be pelletized. Use of dried viable microorganisms (functional ingredient) in the core is disclosed (Col. 3, lines 9-23). Use of binding and plasticizing materials (fats/oils, propylene glycol fatty acid ester) is further disclosed and examples of binding materials are given (Col. 3, lines 30-34). Use of lubricant is disclosed in experiment 2 (Col. 6, formulation table).

7. Okinogo et al. explain the use of sugar/starch compositions to be used for the core of their product. They mention that almost anything edible that can be pelletized may be used in the core of their product including palletized dried viable microorganisms (Col. 3, lines 13-23).

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8. Okonogi et al. disclose the concept of coating their granular product in order to protect it from environmental moisture and atmospheric oxygen. (Col. 2, lines 36-39). They further explain the use of various coating materials, which provide palatable taste, flavor, color and enteric coating. (Col. 5, 17-34; Col. 8, lines 33-46).
9. Okonogi et al. teach making particles by pelletizing various ingredients including saccharides, and acid crystals. They mention that particles of such materials and any other edible material may be prepared by pelletizing these materials. For instance, dried viable microorganisms, a pelletized product of such powder mixes may be used as the core material.
10. They are silent on the water activity (a_w) of their pellets.
11. Klapwijk et al. disclose the process of making supported lactic acid bacterial compositions where the water activity of the supported flora products is 0.3 or less, particularly 0.2 or less. They also mention that improved storage life is provided with water activity values 0.15 or less (Page 3, lines 47-49).
12. Van Lengerich discloses a product that contains encapsulated live organisms. The matrix composition of his invention comprises a plasticizer and a substantial amount of a free flowing mixture (page 3, lines 8-15). The coating of the pellets is discussed in example 2 and 3 (page 35 and 36). He discloses the dimensions of the product where the extruded rope may have a cross sectional diameter 0.5 mm to about 3 mm. Assuming an average pellet diameter of 1.75 mm, the pellet volume is calculated to be about 1.5 mm^3 .

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13. Van Lengerich describes the product to be non-expanded, non-puffed, and substantially non-cellular. It is also mentioned that the starch is substantially ungelatinized, and not substantially destructured or dextrinized. Specific densities of the products are disclosed to be about 0.8 to 1.5 g/cm³ (Page 33, lines 8-13).

14. Van Lengerich teaches of the use of the pellets as food or their incorporation into foods, nutraceuticals and pharmaceuticals. A variety of foods having various moisture levels are mentioned. His product comprises at least one component of the food e.g. yogurt which can contain nonfat dry milk, or gelatin, or lactose (Page 33 line 14 to page 34 line 16).

15. Van Lengerich teaches of the incorporation of pellets containing live micro-organisms into various foods where the food and the pelleted product share at least one ingredient. He mentions that the encapsulated product may be incorporated, with or without grinding, into foods for human or animal consumption. The foods, which are exemplified do share, at least, one component with the granulated product (Page 33, lines 14-23 and page 34, lines 1-2).

9. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of Okonogi et al. by using the teachings of Klapwijk et al. and Van Lengerich to make the probiotic delivery system of the instant application. One would have done so to receive the benefits of a product which could be used as a delivery system for dried viable organisms. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a

reasonable expectation of success in making a probiotic delivery system with characteristics outlined in the instant application.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Arguments regarding Okonogi et al.:

Okonogi discloses that the temperature of the granulating chamber is adjusted depending on the properties of the binding material so that the dried viable microorganism cells are adhered on the surface of the core (Col. 4, lines 28-31). As a result of the adherence, the microorganisms are part of the core. Okonogi does not teach away from an inner matrix including microorganisms. He explains that according to a Japanese prior art, it might be possible to decrease the water content of the product just after manufacturing them, but it is almost impossible to keep the product from moisture and oxygen which necessitates the use of hermetically sealed container in which air is replaced with nitrogen. Okonogi then emphasizes that it goes without saying that additional step (hermetically sealed container with nitrogen) and cost of additional material will occupy a considerable portion of the cost of the product (Col. 2, lines 17-28). Okonogi prepares a core material (granulated sugar) containing dried viable cells of *Bifidobacterium longum* and coats the core with shellac and zein (Col. 8, examples 1 and 2).

Arguments regarding Klapwijk et al.

Klapwijk (EP 0 298 605) teaches the preparation of *Lactobacillus* species (NRRL B-18368), incorporated into a rye flour matrix dried to less than 1% moisture resulting in a water activity of 0.2. This is a core containing *Lactobacilli* which has a low water activity with a shelf life of several months. He mentions that his invention is suitable for the application of other lactic acid bacteria such as *Pediococci*, *Streptococci*, *Leuconostoc* and *Bifidobacteria*. His invention has application in food, animal feed and agricultural industries. His invention is not limited to bread making (Page 2, lines 3-4).

Arguments regarding Van Lengerich

Van Lengerich (WO 99/48372) discloses a probiotic delivery system for *Lactobacillus acidophilus* as an example. The lactic acid bacteria are imbedded in a matrix (ground cookies). Free flowing matrix not containing gelatinized starch does not mean that the water activity is high. In fact the core is dried at low temperature before being coated with shellac. The core has 5.9% moisture (Example 1, page 34-35). In embodiments of his invention, Van Lengerich states, the extruded pieces or pellets may be compressed in conventional tablet presses to obtain compressed version of the extruded pellets (Page 32, lines 11-13).

“[E]ven though product- by -process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE MONTHS** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F 7:30-5:00 ET (First Friday Off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Primary Examiner, Art Unit 4174

Hamid R Badr
Examiner
Art Unit 4174